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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/523,886 03/13/00 GRDINA

D P-01904US1

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HM22/0502

EXAMINER

CHEN, S

ART UNIT	PAPER NUMBER
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1633

DATE MAILED:

05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/523,886

Applicant(s)

GRDINA ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-31 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____.

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-16, drawn to a method for reducing the number of metastasis in an animal exhibiting a primary tumor by administering to said animal a subcytoprotective dose of phosphorothioate or active metabolite thereof, and further administering a **chemotherapy**, classifiable in classes 514 and 544, subclasses 1 and 313, respectively.
 - II. Claims 1-14, 17 and 18, drawn to a method for reducing the number of metastasis in an animal exhibiting a primary tumor by administering to said animal a subcytoprotective dose of phosphorothioate or active metabolite thereof, and further administering a **radiotherapy**, classifiable in classes 514 and 378, subclasses 1 and 65, respectively.
 - III. Claims 1-14, 19 and 20, drawn to a method for reducing the number of metastasis in an animal exhibiting a primary tumor by administering to said animal a subcytoprotective dose of phosphorothioate or active metabolite thereof, and further using a **gene therapy** comprising providing to said animal a nucleotide sequence encoding a tumor suppressor, an inducer of apoptosis, an antisense oncogene, or an angiostatin and other inhibitors of angiogenesis, classifiable in class 514, subclasses 1 and 44.
 - IV. Claims 1-14, 21 and 22, drawn to a method for reducing the number of metastasis in an animal exhibiting a primary tumor by administering to said animal a

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subcytoprotective dose of phosphorothioate or active metabolite thereof, and further using **surgery**, classifiable in classes 514 and 604, subclasses 1 and 20, respectively.

- V. Claims 1-13 and 23-31, drawn to a method for reducing the number of metastasis in an animal exhibiting a primary tumor by administering to said animal a subcytoprotective dose of phosphorothioate or active metabolite thereof, and further monitoring the ability of said phosphorothioate or active metabolite thereof in reducing metastasis, and a method for inhibiting or preventing metastasis in an animal by using said phosphorothioate or active metabolite thereof, classifiable in classes 514 and 435, subclasses 1 and 4, respectively.

Claims 1-13 are generic to groups I-V. Claim 14 is generic to groups I-IV. Note that the generic claims will be examined only to the extent that they encompasses the elected subject matter upon election.

Claims 1-13 link(s) inventions I-V and claim 14 links inventions I-IV . The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional

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application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

2. The inventions are distinct, each from the other because of the following reasons:

Groups I-V are distinct from each other because they are drawn to materially distinct methods which differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Chemotherapy, radiotherapy, gene therapy, surgery and a method for monitoring the ability of the phosphorothioate or active metabolite thereof in reducing metastasis are different methods that differ at least in objectives, method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Thus, groups I-V are patentably distinct from each other. They have different classifications and require separate search.

Upon election of **group III**, a further restriction is required as follows:

Since the nucleotide sequence encoding a tumor suppressor, an inducer of apoptosis, an antisense oncogene, or an angiostatin and other inhibitors of angiogenesis represent different and distinct group of genes or cDNAs encoding different proteins. The chemical structures of

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different group of genes are different from each other and their gene product functions also differ from each other. Thus, they are patentably distinct from each other and require separate search. Applicant is required to elect **one** group from the following groups of genes for consideration by examiner:

- I. tumor suppressor
- II. inducer of apoptosis
- III. antisense oncogene
- IV. angiostatin and other inhibitors of angiogenesis

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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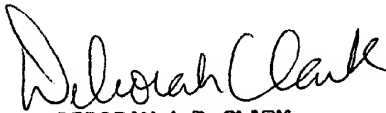
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.


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